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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,219	03/28/2001	Jean-Michel Bernardon	016800-425	7072

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BURNS DOANE SWECKER & MATHIS L L P  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

EXAMINER

CHANG, CELIA C

ART UNIT PAPER NUMBER

1625

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/719,219

**Applicant(s)**

BERNARDON ET AL.

**Examiner**

Celia Chang

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 11/04/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-3,9,12 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1 and 15-17 is/are rejected.
- 7) ☐ Claim(s) 2,3,9,12 and 18-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Amendment and response filed by applicants dated Nov. 5, 2004 have been entered and considered carefully.

Claims 4-8, 10-11, 13-14 have been canceled. Claims 1-3, 9, 12 and 15-20 are pending.

2. The rejections of claims 1-3, 9, 12, 18-20 under 35 USC 112 second paragraph is maintain for the currently amended claim 1.

Please note that when amending claim 1, R2 and R3 radical being linked to form a 6 membered saturated ring, the term “depend” was erroneously used for a structural feature. R2 and R3 can connect or attach to the phenyl ring but are not depend on the ring. Correction of ambiguity is required.

3. The rejection of claims 1-3, 9, 12, 17-20 under 35 USC 112 first paragraph is dropped in view of the limitation to the elected compounds which are neither anticipated nor rendered obvious by the art of record.

4. The rejection of claims 15-17 under 35 USC 112 first paragraph is maintained for reasons of record.

In the previous office action, it was clearly delineated under the Wand’s factors that in view of the high degree of unpredictability of pharmaceutical composition and the therapeutic method in using such compounds, the specification lacks written description and enablement under the requirement of 112 first paragraph.

The currently amended claims 15-17 lack written description and enablement as delineated in the previous office action.

A article by Lendaris et al. was attached to explain that such claims are considered being “reach through” claims because the are claims being drawn to “research may identify a mechanism of disease action such as ..... while these discoveries may allow the development of screening assays to identify drug candidates, the actual products, the drug themselves, have not yet been developed”.

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In the instant case, it was **disclose** in the specification that the instantly claimed compounds find *application.....dermatological complaints, .....combating aging...*"(see page 1, 15-17) without any data or factual evidence that such compound can be administered in any form. Please note that material containing Selenium is highly toxic (Madhaven et al.). While appropriately formulated for topical application finds utility for the compounds to be used in hair or body hygiene, application in therapeutic methods requires more in view of such toxicity and unpredictability. Especially, other than complaints known to be possibly associated with keratinization or other dermatological complaints were listed on the above mention pages, no explicit pathology, related dosage/efficacy information or route/site of administration were disclosed. Lacking such specific description and enablement, the public is offered mere drug candidates passing the screen assays without actual enablement. The efficacy in obviating what kind of pathology or how such pathology can be relieved finds neither description nor enablement in the specification.

Especially, in the currently amended scope of claims 15-17, the therapeutic methods included treating all malignant and immunoallergic conditions, chronological ageing, cancerous and precancerous states etc. are considered incredible utility.

5. Claims 2-3, 9, 12, 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable when the 112 issues of the base claim is resolved.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Feb. 7, 2005



Celia Chang  
Primary Examiner  
Art Unit 1625